| 0-1-1-1 //- | ACLIDANICCIONI | | | | _ |
|-------------|----------------|-----------|---------------|-------------|---|
| Onginai (io | r SUBMISSION) | - printed | on 07.11,2003 | 03:32:28 PM | 1 |

| 0 | For receiving Office use only | |
|---------|--|------------------------------------|
| 0-1 | | |
| 0-1 | International Application No. | : |
| 0-2 | International Filing Date | : |
| | | |
| 0-3 | Name of receiving Office and "PCT | |
| | International Application" | |
| | | |
| | LE DOTINGUES DE LA CONTRACTION DEL LA CONTRACTION DE LA CONTRACTIO | |
| 0-4 | Form - PCT/RO/101 PCT Request | |
| 0-4-1 | Prepared using | PCT-EASY Version 2.92 |
| | | (updated 01.07.2003) |
| 0-5 | Petition | |
| | The undersigned requests that the present international application be | · · |
| | processed according to the Patent | |
| 0-6 | Cooperation Treaty | |
| 0-0 | Receiving Office (specified by the applicant) | United States Patent and Trademark |
| | A - I' I'- | Office (USPTO) (RO/US) |
| 0-7 | Applicant's or agent's file reference | PU5025WO/KLP |
| 1 | Title of invention | PHARMACEUTICAL COMPOSITIONS |
| 11 | Applicant | |
| II-1 | This person is: | applicant only |
| 11-2 | Applicant for | all designated States except US |
| 11-4 | Name | GLAXO GROUP LIMITED |
| 11-5 | Address: | Glaxo Wellcome House |
| | | Berkeley Avenue |
| • | | Greenford, Middlesex UB6 0NN |
| | | United Kingdom |
| 11-6 | State of nationality | GB |
| II-7 | State of residence | GB . |
| II-8 | Telephone No. | 919-483-2370 (US number) |
| 11-9 | Facsimile No. | 919-483-7988 (US number) |
| 111-1 | Applicant and/or inventor | |
| 111-1-1 | This person is: | applicant only |
| III-1-2 | Applicant for | all designated States except US |
| III-1-4 | Name | SMITHKLINE BEECHAM CORPORATION |
| 111-1-5 | Address: | One Franklin Plaza |
| | | Philadelphia, PA 19101 |
| | | United States of America |
| III-1-6 | State of nationality | US America |
| III-1-7 | State of residence | 1 7 7 |
| | 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - 1 - | US |



| 111-2 | Applicant and/or inventor | | |
|---------|---------------------------|----------------------------------|--|
| 111-2-1 | This person is: | applicant and inventor | |
| 111-2-2 | Applicant for | US only | |
| 111-2-4 | Name (LAST, First) | GOODSON, Gary, Wayne | |
| III-2-5 | Address: | c/o GlaxoSmithKline | |
| | | Five Moore Drive | |
| | | PO Box 13398 | |
| | | Research Triangle Park, NC 27709 | |
| | | United States of America | |
| 111-2-6 | State of nationality | US | |
| 111-2-7 | State of residence | us | |
| III-3 | Applicant and/or inventor | | |
| III-3-1 | This person is: | applicant and inventor | |
| 111-3-2 | Applicant for | US only | |
| 111-3-4 | Name (LAST, First) | FLOYD, Alison, Green | |
| 111-3-5 | Address: | c/o GlaxoSmithKline | |
| | | Five Moore Drive | |
| | | PO Box 13398 | |
| | | Research Triangle Park, NC 27709 | |
| | | United States of America | |
| 111-3-6 | State of nationality | US | |
| 111-3-7 | State of residence | บร | |
| 111-4 | Applicant and/or inventor | · | |
| III-4-1 | This person is: | applicant and inventor | |
| 111-4-2 | Applicant for | US only | |
| 111-4-4 | Name (LAST, First) | NAVY, Cecilia, Carpenter | |
| 111-4-5 | Address: | c/o GlaxoSmithKline | |
| | | Five Moore Drive | |
| | | PO Box 13398 | |
| | | Research Triangle Park, NC 27709 | |
| | | United States of America | |
| III-4-6 | State of nationality | us | |
| III-4-7 | State of residence | US | |



| IV-1 | Agent or common representative; or address for correspondence | |
|--------|--|--|
| | The person identified below is | agent |
| | hereby/has been appointed to act on | agono . |
| | behalf of the applicant(s) before the competent International Authorities as: | |
| IV-1-1 | Name (LAST, First) | LEVY, David, J |
| IV-1-2 | Address: | GlaxoSmithKline |
| | | Corporate Intellectual Property |
| | | Department |
| | | Five Moore Drive |
| | | PO Box 13398 |
| | 1 | Research Triangle Park, NC 27709 |
| | · | United States of America |
| IV-1-3 | Telephone No. | 919-483-2370 (US Number) |
| IV-1-4 | Facsimile No. | 919-483-7988 (US Number) |
| IV-1-5 | Agent's registration No. | 27,655 |
| IV-2 | Additional agent(s) | additional agent(s) with same address as |
| | | first named agent |
| IV-2-1 | Name(s) | PRUS, Karen, L. (39,337) |
| V | Designation of States | |
| V-1 | Regional Patent | AP: GH GM KE LS MW MZ SD SL SZ TZ UG ZM |
| | (other kinds of protection or treatment, if any, are specified between parentheses | ZW and any other State which is a |
| | after the designation(s) concerned) | Contracting State of the Harare Protocol |
| | | and of the PCT |
| | | EA: AM AZ BY KG KZ MD RU TJ TM and any |
| | | other State which is a Contracting State |
| | | of the Eurasian Patent Convention and of |
| | | the PCT |
| | | EP: AT BE BG CH&LI CY CZ DE DK EE ES FI |
| | | FR GB GR HU IE IT LU MC NL PT RO SE SI |
| | | SK TR and any other State which is a |
| | | Contracting State of the European Patent |
| | | Convention and of the PCT |
| | | OA: BF BJ CF CG CI CM GA GN GQ GW ML MR |
| | | NE SN TD TG and any other State which is |
| | | a member State of OAPI and a Contracting |
| 1/0 | No. | State of the PCT |
| V-2 | National Patent (other kinds of protection or treatment, if any, are specified between parentheses after the designation(s) concerned) | AE AG AL AM AT AU AZ BA BB BG BR BY BZ |
| | | CA CH&LI CN CO CR CU CZ DE DK DM DZ EC |
| | | EE EG ES FI GB GD GE GH GM HR HU ID IL |
| | | IN IS JP KE KG KP KR KZ LC LK LR LS LT |
| | | LU LV MA MD MG MK MN MW MX MZ NI NO NZ |
| | | OM PG PH PL PT RO RU SC SD SE SG SK SL |
| | | SY TJ TM TN TR TT TZ UA UG US UZ VC VN |
| | <u> </u> | YU ZA ZM ZW |

| V-5 | Precautionary Designation Statement | |
|---|---|--|
| | In addition to the designations made | |
| | under items V-1, V-2 and V-3, the | · |
| | applicant also makes under Rule 4.9(b) all designations which would be | |
| | permitted under the PCT except any | |
| | designation(s) of the State(s) indicated | |
| | under item V-6 below. The applicant | |
| | declares that those additional designations are subject to confirmation | · |
| | and that any designation which is not | |
| | confirmed before the expiration of 15 | |
| | months from the priority date is to be regarded as withdrawn by the applicant | |
| | at the expiration of that time limit. | |
| /-6 | Exclusion(s) from precautionary designations | NONE |
| /1-1 | Priority claim of earlier national | |
| | application | |
| /I-1-1 | Filing date | 08 November 2002 (08.11.2002) |
| /I-1-2 | Number | 60/425,182 |
| /1-1-3 | Country | US |
| /1-2 | Priority document request | |
| | The receiving Office is requested to | and a |
| | | VI-1 |
| | prepare and transmit to the International | VI-I |
| | prepare and transmit to the International Bureau a certified copy of the earlier | VI-I |
| | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): | VI-I |
| | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as | European Patent Office (EPO) (ISA/EP) |
| /111 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations | |
| VII-1 VIII VIII-1 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations Declaration as to the identity of the inventor | European Patent Office (EPO) (ISA/EP) |
| /III /III-1 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations Declaration as to the identity of the inventor Declaration as to the applicant's | European Patent Office (EPO) (ISA/EP) Number of declarations |
| /III /III-1 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations Declaration as to the identity of the inventor Declaration as to the applicant's entitlement, as at the international filing | European Patent Office (EPO) (ISA/EP) Number of declarations - |
| /III /III-1 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations Declaration as to the identity of the inventor Declaration as to the applicant's | European Patent Office (EPO) (ISA/EP) Number of declarations - |
| /III /III-1 /III-2 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations Declaration as to the identity of the inventor Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent Declaration as to the applicant's | European Patent Office (EPO) (ISA/EP) Number of declarations - |
| /III /III-1 /III-2 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations Declaration as to the identity of the inventor Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent Declaration as to the applicant's entitlement, as at the international filing | European Patent Office (EPO) (ISA/EP) Number of declarations |
| /III /III-1 /III-2 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations Declaration as to the identity of the inventor Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier | European Patent Office (EPO) (ISA/EP) Number of declarations |
| /III /III-1 /III-2 /III-3 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations Declaration as to the identity of the inventor Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application Declaration of inventorship (only for the | European Patent Office (EPO) (ISA/EP) Number of declarations |
| /III /III-1 /III-2 /III-3 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations Declaration as to the identity of the inventor Declaration as to the applicant's entitlement, as at the international filling date, to apply for and be granted a patent Declaration as to the applicant's entitlement, as at the international filling date, to claim the priority of the earlier application Declaration of inventorship (only for the purposes of the designation of the | European Patent Office (EPO) (ISA/EP) Number of declarations |
| VIII-1 VIII-2 VIII-3 VIII-4 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations Declaration as to the identity of the inventor Declaration as to the applicant's entitlement, as at the international filling date, to apply for and be granted a patent Declaration as to the applicant's entitlement, as at the international filling date, to claim the priority of the earlier application Declaration of inventorship (only for the purposes of the designation of the United States of America) | European Patent Office (EPO) (ISA/EP) Number of declarations |
| /III /III-1 /III-2 /III-3 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations Declaration as to the identity of the inventor Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application Declaration of inventorship (only for the purposes of the designation of the United States of America) Declaration as to non-prejudicial | European Patent Office (EPO) (ISA/EP) Number of declarations |
| /III /III-1 /III-2 /III-3 /III-4 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations Declaration as to the identity of the inventor Declaration as to the applicant's entitlement, as at the international filling date, to apply for and be granted a patent Declaration as to the applicant's entitlement, as at the international filling date, to claim the priority of the earlier application Declaration of inventorship (only for the purposes of the designation of the United States of America) | European Patent Office (EPO) (ISA/EP) Number of declarations |
| /III /III-1 /III-2 /III-3 /III-4 /III-5 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations Declaration as to the identity of the inventor Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application Declaration of inventorship (only for the purposes of the designation of the United States of America) Declaration as to non-prejudicial disclosures or exceptions to lack of novelty Check list | European Patent Office (EPO) (ISA/EP) Number of declarations - - number of sheets electronic file(s) attached |
| /III /III-1 /III-2 /III-3 /III-4 /III-5 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations Declaration as to the identity of the inventor Declaration as to the applicant's entitlement, as at the international filling date, to apply for and be granted a patent Declaration as to the applicant's entitlement, as at the international filling date, to claim the priority of the earlier application Declaration of inventorship (only for the purposes of the designation of the United States of America) Declaration as to non-prejudicial disclosures or exceptions to lack of novelty Check list Request (including declaration sheets) | European Patent Office (EPO) (ISA/EP) Number of declarations - - - |
| /III /III-1 /III-2 /III-3 /III-4 /III-5 X X-1 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations Declaration as to the identity of the inventor Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application Declaration of inventorship (only for the purposes of the designation of the United States of America) Declaration as to non-prejudicial disclosures or exceptions to lack of novelty Check list Request (including declaration sheets) Description | European Patent Office (EPO) (ISA/EP) Number of declarations - - number of sheets electronic file(s) attached |
| /III /III-1 /III-2 /III-3 /III-4 /III-5 X X-1 X-2 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations Declaration as to the identity of the inventor Declaration as to the applicant's entitlement, as at the international filling date, to apply for and be granted a patent Declaration as to the applicant's entitlement, as at the international filling date, to claim the priority of the earlier application Declaration of inventorship (only for the purposes of the designation of the United States of America) Declaration as to non-prejudicial disclosures or exceptions to lack of novelty Check list Request (including declaration sheets) | European Patent Office (EPO) (ISA/EP) Number of declarations - - number of sheets electronic file(s) attached - |
| /III /III-1 /III-2 /III-3 /III-4 /III-5 X X-1 X-2 X-3 X-4 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations Declaration as to the identity of the inventor Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application Declaration of inventorship (only for the purposes of the designation of the United States of America) Declaration as to non-prejudicial disclosures or exceptions to lack of novelty Check list Request (including declaration sheets) Description Claims Abstract | European Patent Office (EPO) (ISA/EP) Number of declarations number of sheets electronic file(s) attached 5 17 - |
| /III /III-1 /III-2 /III-3 | prepare and transmit to the International Bureau a certified copy of the earlier application(s) identified above as item(s): International Searching Authority Chosen Declarations Declaration as to the identity of the inventor Declaration as to the applicant's entitlement, as at the international filing date, to apply for and be granted a patent Declaration as to the applicant's entitlement, as at the international filing date, to claim the priority of the earlier application Declaration of inventorship (only for the purposes of the designation of the United States of America) Declaration as to non-prejudicial disclosures or exceptions to lack of novelty Check list Request (including declaration sheets) Description Claims | European Patent Office (EPO) (ISA/EP) Number of declarations - - number of sheets electronic file(s) attached 5 17 - 2 |

PU5025WO/KLP

| | Accompanying items | paper document(s) attached | electronic file(s) attached |
|----|--|----------------------------|-----------------------------|
| 3 | Fee calculation sheet | / | - |
| 17 | PCT-EASY diskette | - | Diskette |
| 8 | Other (specified): | PCT POA for Glaxo | - |
| | | Group Limited and | |
| | | SmithKline Beecham | 1. |
| | | Corp | 1 |
| 18 | Other (specified): | Copy of Corp | - |
| | | Resolutions for GGL | |
| | | and SBC | |
| 8 | Other (specified): | PCT POA for | - |
| | | inventors: Goodson, | |
| | | Floyd and Navy | į |
| 9 | Figure of the drawings which should accompany the abstract | | |
| 0 | Language of filing of the international application | English | |
| | Signature of applicant, agent or common representative | Javan L. Prus | · |
| 1 | Name (LAST, First) | PRUS, Karen, L. | |

FOR RECEIVING OFFICE USE ONLY

| 10-1 | Date of actual receipt of the purported international application | |
|--------|---|--------|
| 10-2 | Drawings: | · |
| 10-2-1 | Received | * |
| 10-2-2 | Not received | |
| 10-3 | Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application | |
| 10-4 | Date of timely receipt of the required corrections under PCT Article 11(2) | |
| 10-5 | International Searching Authority | ISA/EP |
| 10-6 | Transmittal of search copy delayed until search fee is paid | |

FOR INTERNATIONAL BUREAU USE ONLY

| 11-1 | Date of receipt of the record copy by | |
|------|---------------------------------------|--|
| | the International Bureau | |
| | the international buleau | |